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21 MAY 1998

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The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

P/657

2. Patent application number
(The Pate

9810799.8

21 MAY 1998

3. Full nam ...ess and postcode of the or of each applicant *(underline all surnames)*

THE BOOTS COMPNAY PLC
1 THANE ROAD WEST
NOTTINGHAM
NG2 3AA

Patents ADP number *(if you know it)*

7325301001

If the applicant is a corporate body, give the country/state of its incorporation

UNITED KINGDOM

4. Title of the invention

ANTIMICROBIAL AGENT

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

DR M A THACKER
THE BOOTS COMPANY PLC
GROUP PATENTS DEPARTMENT
D31
1 THANE ROAD WEST
NOTTINGHAM
NG2 3AA

Patents ADP number *(if you know it)*

2350400 4

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Claim(s)	1
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Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature MAThacker Date 20/5/98

12. Name and daytime telephone number of person to contact in the United Kingdom DR M A THACKER - 0115 959 4544

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ANTIMICROBIAL AGENT

This invention teaches the use of a modified form of zinc oxide as an agent to inhibit microbial growth.

Micro-organisms, present upon the skin exacerbate many minor human afflictions, such as acne, dandruff and athletes foot. Despite the considerable amount of research conducted upon these subjects, these are still common complaints. Efforts have focused upon developing agents which will kill off the micro-organisms, and are suitable for application to the human body. Not only do micro-organisms continuously develop resistance but many successful antimicrobials cause burning or irritation to the skin. Thus, there is an enormous need for new antimicrobials.

This invention discloses the new use of a modified form of zinc oxide as an antimicrobial agent. The zinc oxide has a surface area between $30m^2/g$ and $100m^2/g$, preferably greater than $90m^2/g$. The zinc oxide particles used in this invention have a diameter between 0.1 and 200µm. Hereinafter, such zinc oxide particles shall be known as "high surface area zinc oxide".

The production of such zinc oxides is well documented.

WO 95/04704 (Harcros)

This patent discloses a method for the production of zinc oxide in the form of discrete particles which have an average particle size of 0.08µm or less in diameter and a surface area $>12.5m^2/g$. The zinc oxide produced is found to be particularly good for as an additive for scattering/absorbing UV light.

S. Tichy, SOFW - Journal 119 Jahrgang 8/93

This article teaches a method for producing zinc oxide with a particle size of 0.20μm and a surface area of 50-150m^2/g.

Liu et al - Journal of Materials Science 21 (1986) 3698-3702

This describes another method of producing zinc oxide particles with a diameter of 0.15μm and a surface area of about 50m^2/g.

These articles are but a small selection from a large number of articles detailing the manufacture of high surface area zinc oxide particles.

Surprisingly, it has been found that high surface area zinc oxide is a potent agent for stopping microbial growth. *In vitro* trials have demonstrated its great efficacy against the micro-organisms responsible for a number of common human afflictions. However, for them to be effective in use, they must be applied to the body.

Many antimicrobials are harsh reagents that cause burning and irritation to human skin, and so are unsuitable for application to the human body. High surface area zinc oxide is a mild reagent which does not cause burning and irritation to the skin. Thus it is suitable for incorporation into formulations designed to be applied to human skin.

Because of its high potency and sensitivity upon the skin, high surface area zinc oxide may be included in formulations designed to treat some of the more common human afflictions which are microbial in origin or exacerbated by subsequent microbial growth.

Microbes are commonly taken to mean any organism too small to be seen unless by microscopy. For the purposes of this invention it is further defined to include bacteria and microscopic fungi. Microscopic fungi is defined to include yeasts.

The present invention provides topical antimicrobial compositions containing a cosmetically acceptable diluent or carrier, and an antimicrobially effective amount of high surface area zinc oxide, having a surface area between $30m^2/g$ and $100m^2/g$ and a particle size with a diameter between 0.1 and 200μm.

Preferably the surface area of the high surface area zinc oxide is greater than $90m^2/g$ and the particle size is between 0.1 and 20.5μm.

In a preferred topical formulation, the high surface area zinc oxide is present from 1 to 10%, preferably 3 to 8%, most preferably 4 to 6% by weight of the total composition.

Acne is a common affliction of many people in their teenage years and sometimes beyond. As a result of puberty, teenagers often have increased levels of sebum. The initial inflammation of the follicle wall in the development of acne results from the presence of free fatty acids derived from the sebum. The normal bacterial flora in the sebaceous duct produce the enzymes responsible for splitting triglycerides in the sebum and releasing these fatty acids. The main micro-organisms in the sebaceous duct are *Propionibacterium acnes* and one or two species of *Staphylococcus aureus*. Therefore in the presence of excess sebum these micro-organisms result in the development of acne.

Most approaches to a cure for acne focus on trying to absorb the excess sebum or to act on the bacteria present.

High surface area zinc oxide has been found to inhibit the growth of *Staphylococcus aureus* and *Propionibacterium acnes*. By inhibiting their growth, less of the sebum is split into the free fatty acids which act to inflame the follicle wall. It may be used as a bacteriostatic agent. So high surface area zinc oxide may be used to treat acne. High surface area zinc oxide may be used in the preparation of a medicament for the treatment of acne.

Athletes foot is the loose term applied to a skin eruption on the foot, usually between the toes. It is a cutaneous fungal infection, most commonly caused by *Tricophyton rubrum*, *Tricophyton mentagrophytes* or *Epidermophyton floccosum*. In addition to the effect of the micro-organisms, other factors such as wetness or an increase in temperature can contribute to disease development by providing ideal conditions for the initiation and growth of fungal infections.

The condition is commonly treated by careful foot hygiene, removing the damp conditions helpful to fungal growth and by the use of antifungal agents. High surface area zinc oxide has been found to be a potent antifungal agent. This invention teaches high surface area zinc oxide as a potent antifungal agent and the use of high surface area zinc oxide as a treatment for athletes foot. High surface area zinc oxide may be used in the preparation of a medicament for the treatment of athletes foot.

Dandruff is a common human condition characterised by the excess scaling of scalp tissue. *Pityrosporum ovale* is a yeast whose growth is accelerated as a result of the dandruff condition, resulting in secondary infection and a worsening of the condition.

It has been found that high surface area zinc oxide is a potent agent against microbial growth particularly at inhibiting the growth of *P.ovale* and *S.aureus*. So high surface area zinc oxide may be used to prevent microbial

S.aureus. So high surface area zinc oxide may be used to prevent microbial growth occurring during dandruff conditions. High surface area zinc oxide may be used in the preparation of a medicament for the treatment of dandruff.

Nappy rash, the skin eruption which tends to occur on the buttocks of infants is due to infrequent changing of soiled nappies. The condition is often worsened by secondary infection with *Candida albicans*. To prevent this condition, nappies are changed regularly and care is taken to ensure that the baby's bottom is dried properly. The buttocks are commonly treated with an agent to absorb any surplus liquid.

High surface area zinc oxide has been found to be highly efficacious when used in the treatment of nappy rash. It is a potent antifungal, and by stopping the growth of *Candida albicans* it prevents the associated secondary infection.

In an embodiment of the invention, the compositions may be formulated as a gel. Such gels may be formulated in a manner known to those skilled in the art, and may include, but not limited to:-

a) antibacterials such as dichlorobenzyl alcohol, triclosan, chlorhexidine digluconate and salicylic acid;
b) oil absorbers such as silica;
c) alcohols such as denatured ethanol, isopropyl alcohol;
d) humectants such as panthenol, butylene glycol, glycerin and propylene glycol;
e) preservatives such as methyldibromo glutaronitrile, phenoxyethanol, magnesium chloride, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone or any paraben, for example such as methylparaben, ethyl paraben and propyl paraben;
f) solubilisers such as polysorbate 20, polyethylene glycol-40 hydrogenated castor oil;

g) thickeners such as xanthan gum, hydroxyethylcellulose, sodium magnesium silicate;

h) emollients such as glycerin, propylene glycol and butylene glycol.

In a further embodiment of the invention, the cosmetic formulation may be a skin wash, such as a cleanser, moisturiser, face wash, lotion, stick or cream. The composition may be formulated in a manner known to those skilled in the art. Such compositions may include, though not limited to:-

a) alcohols such as isopropyl myristate, stearyl alcohol, denatured ethanol.

b) emulsifiers such as steareth-2, glyceryl stearate, hydrogenated vegetable glycerides, steareth-21, ceteth-20, cetyl alcohol, cetearyl alcohol, stearic acid, paraffin, stearyl alcohol, polawax, tribehenin, ceteareth-7, ceteth-5.

c) emollients such as Polypropylene Glycol 5-ceteth-20, methyl gluceth-10, Dicaprytyl maleate, cetearyl isononanoate, silicones, paraffinum liquidum and octyl palmitate petrolatum, dioctyl maleate, isohexadecane, cetearyl octanoate and isopropyl myristate.

d) solubilisers such as polysorbate 80, polysorbate 20, polyethylene glycol-40 hydrogenated castor oil, any polysorbate.

e) antibacterials such as triclosan, chlorhexidine digluconate, salicylic acid and dichlorobenzyl alcohol.

f) thickeners such as hydroxyethylcellulose, xanthan gum, sodium magnesium silicate, magnesium aluminium silicate and cellulose.

g) detergents such as sodium laureth sulfate, ammonium lauryl sulfate, magnesium lauryl sulfate, disodium undecylenamido MEA-sulfosuccinate.

h) preservatives such as phenoxyethanol , 2-bromo-2-nitropropane-1,3-diol, ~~methyldibromo glutaronitrile, imidazolidinyl urea,~~ magnesium chloride, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, or any paraben, for example such as propyl paraben, butyl paraben, ethyl paraben, methyl paraben.

i) absorbents such as hydrated silica, clays, talcs.

j) antioxidants such as butylated hydroxytoluene or butylated hydroxyacetone.

k) moisturisers such as butylene glycol, propylene glycol, sorbitol and glycerin, panthenol, sodium hyaluronate, sodium PCA.

In another embodiment of the invention the composition may be formulated as a shampoo. Such a composition may be formulated in a manner known to those skilled in the art, and may include, but not limited to:-

a) thickeners such as xanthan gum, hydroxyethylcellulose, laureth 3, sodium chloride, polyethylene glycol-55 propylene glycol oleate and polyethylene glycol-40 hydrogenated castor oil;

b) pearlising agents such as formaldehyde, stearic acid, cocamide MEA, glycol distearate glycol stearate and methyldibromo glutaronitrile;

c) solubilisers such as laureth 3, polyethylene glycol-40 hydrogenated castor oil,

polyethylene glycol-55 propylene glycol oleate and propylene glycol;

d) conditioners such as polyquaternium-39, polyquaternium-7, polyquaternium-10 and hydroxypropyl guar hydroxypropylthrimonium chloride;

e) surfactants such as cocamidopropyl betaine and sodium laureth sulphate.

The efficacy of high surface area zinc oxide as an antimicrobial agent has been demonstrated by *in vivo* and *in vitro* trials. The suitability of high surface area zinc oxide for the purposes stated herein has been demonstrated by trials of standard control formulations against those formulations containing high surface area zinc oxide.

The invention is further disclosed by way of the following, non limiting examples. Unless otherwise stated, the zinc oxide used in the following formulations has a surface area greater than $90m^2/g$ and the particles have an average diameter of 10.47µm.

Example 1 - Skin Treatment Gel (Control)

Ingredient	%
Alcohol (denatured)	10.00
Allantoin	0.10
Glycerin	1.00
Butylene Glycol	4.00
Xanthan Gum	1.00
Phenoxyethanol	0.20
Hydrated silica	0.50
Dichlorobenzyl alcohol	0.10
Colour	qs
Benzophenone - 4	0.10
Purified Water	to 100
Panthenol	0.50

Xanthan gum, dispersed in 2% of the butylene glycol was added to some of the purified water, and mixed together for 30 minutes. Allantoin, sequestrene and panthenol were added, and the mixture was then stirred for 5 minutes. The mixture was cooled to 35°C, then premixed phenoxyethanol and glycerin was added to the mixture, followed by premixed alcohol (denatured) and purified water, followed by premixed dichlorobenzyl alcohol and butylene glycol. The mixture was then stirred. Benzophenone-4 and water were then added with stirring, followed by hydrated silica. The mixture was stirred, cooled to below 35°C and then the colour was added. Cold water was added to the bulk, and the mixture was stirred for a further 30 minutes.

Example 2 - Skin Treatment Gel + High Surface Area Zinc Oxide

Ingredients	%
Alcohol (denatured)	10.00
Allantoin	0.10
Glycerin	1.00
Butylene Glycol	4.00
Xanthan Gum	1.00
Phenoxyethanol	0.20
Hydrated silica	0.50
Dichlorobenzyl alcohol	0.10
Colour	qs
Benzophenone - 4	0.10
Purified Water	to 100
Panthenol	0.50
High Surface Area Zinc Oxide	5

Xanthan gum, dispersed in 2% of the butylene glycol was added to some of the purified water, and mixed together for 30 minutes. Allantoin, sequestrene and panthenol were added and the mixture was then stirred for 5 minutes. The mixture was cooled to 35°C, then premixed phenoxyethanol and glycerin was added to the mixture, followed by premixed alcohol (denatured) and purified water, followed by premixed dichlorobenzyl alcohol and butylene glycol. The mixture was then stirred. Benzophenone-4 and water were then added with stirring, followed by hydrated silica and high surface area zinc oxide. The mixture was stirred, cooled to below 35°C and then the colour was added. Cold water was added to the bulk, and the mixture stirred for a further 30 minutes.

Example 3 - Non-oily Moisturiser (Control)

Ingredients	%
Colour	qs
Perfume	0.10
Triclosan	0.10
Allantoin	0.10
Phenoxyethanol	0.20
Hydroxyethylcellulose	2.00
Polysorbate 20	1.00
Butylene Glycol	3.50
Glycerin	4.50
Purified Water	to 100

Stage 1

Hydroxyethylcellulose was added to purified water and then homogenised for at least 30 minutes. The homogeniser was switched off and with stirring allantoin and phenoxyethanol, which had been previously dissolved in glycerin and butylene glycol, were added.

Stage 2

Butylene glycol and glycerin were warmed together to 45°C. Then with stirring triclosan was added, stirred and completely dissolved and cooled to 35°C.

Stage 3

Using a homogeniser, stage 2 was added to stage 1 and homogenised for 10 minutes. The perfume, previously dispersed in polysorbate 20 was then added and stirred in well. The colour was added and the emulsion was then

homogenised for a further 5 to 10 minutes until the product was smooth. Purified water, sufficient to make the formulation up to bulk, was then added.

Example 4 - Non-oily Moisturiser + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5
Colour	qs
Perfume	0.10
Triclosan	0.10
Allantoin	0.10
Phenoxyethanol	0.20
Hydroxyethylcellulose	2.00
Polysorbate 20	1.00
Butylene Glycol	3.50
Glycerin	4.50
Purified Water	to 100

Stage 1

Hydroxyethylcellulose was added to purified water and then homogenised for at least 30 minutes. The homogeniser was switched off and with stirring allantoin and phenoxyethanol, which had been previously dissolved in glycerin and butylene glycol, were added.

Stage 2

Butylene glycol and glycerin were warmed together to 45°C. Then with stirring, triclosan and high surface area zinc oxide were added, stirred and completely dissolved and cooled to 35°C.

Stage 3

Using a homogeniser, stage 2 was added to stage 1 and homogenised for 10 minutes. The perfume, previously dispersed in polysorbate 20 was then

added and stirred in well. The colour was added and the emulsion was then homogenised for a further 5 to 10 minutes until the product was smooth. Purified water, sufficient to make the formulation up to bulk, was then added.

Example 5 - Cleansing Lotion (Control)

Ingredients	%
Purified Water	to 100
Colours	qs
Melaleuca alternifolia	0.50
Polypropylene glycol- 5-ceteth-20	3.25
Polysorbate 80	0.20
Citric acid	0.12
Disodium Phosphate	0.38
Triclosan	0.30
Butylene Glycol	0.20
Alcohol (denatured)	48.00

Stage 1

Alcohol (denatured) and triclosan were mixed together until homogeneous. Water was added and mixed well. Butylene glycol was then added and the mixture stirred.

Stage 2

To a suitable stainless steel container disodium phosphate and water were added and warmed to 55-60°C with stirring. Then some water was added, with stirring and then the mixture was allowed to cool.

Stage 3

When the temperature of stage 2 had reached 20-25°C it was added to stage 1 with stirring. Citric acid was added and mixed well. To a suitable stainless steel container polypropylene glycol-5-ceteth-20 and melaleuca alternifolia were added. This was then mixed thoroughly and added to the main vessel. In a suitable container polypropylene glycol-5-ceteth-20 and polysorbate 80 were premixed and this was then added to the main vessel. Sufficient colour was added, followed by water to make up to bulk.

Example 6 - Cleansing Lotion + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Purified Water	to 100
Colours	qs
Melaleuca alternifolia	0.50
Polypropylene- 5-ceteth- 20	3.25
Polysorbate 80	0.20
Citric acid	0.12
Disodium Phosphate	0.38
Triclosan	0.30
Butylene Glycol	0.20
Alcohol (denatured)	48.00

Stage 1

Alcohol (denatured) and triclosan were mixed together until homogeneous. Water was added and mixed well. Butylene glycol was then added and the mixture stirred.

Stage 2

To a suitable stainless steel container disodium phosphate and water were added and warmed to 55-60°C with stirring. Then some water was added, with stirring and the mixture was then allowed to cool.

Stage 3

When the temperature of stage 2 had reached 20-25°C it was added to stage 1 with stirring. Citric acid was added and mixed well. To a suitable stainless steel container polypropylene glycol-5-ceteth-20, melaleuca alternifolia and high surface area zinc oxide were added. This was then mixed thoroughly and added to the main vessel. In a suitable container polypropylene glycol-5-ceteth-20 and polysorbate 80 were premixed and this was then added to the main vessel. The colour was added, followed by water to make up to bulk.

Example 7 - Cleansing Wash (Control)

Ingredients	%
Cocamidopropyl betaine 30%	5.00
Benzophenone - 4	0.10
Sodium citrate	0.60
Disodium undecylenamido MEA-sulfosuccinate solution	1.00
Triclosan	0.20
Salt	1.00
Laureth - 3	2.00
Sodium laureth sulphate	47.20
Colour	qs
Melaleuca alternifolia	0.500
Phenoxyethanol	0.15
Purified Water	to 100
Citric acid	0.10

Stage 1

In a vessel sodium laureth sulphate and melaleuca alternifolia were mixed until uniform.

Stage 2

In the base pan the triclosan was dispersed in cocamidopropyl betaine 30% and stirred for 5 minutes. The purified water was added and stirred well. Citric acid was added and stirred until dissolved followed by sodium citrate, which was stirred until dissolved and then stirred for a further 10 minutes. The mixture was cooled to 30-35°C. Then premixed phenoxyethanol in water, followed by benzophenone-4 in water were added. The colour was added followed by saline solution and water to make up to bulk.

Example 8 - Cleansing Wash + High Surface Area Zinc Oxide

Ingredients	%
Cocamidopropyl betaine 30%	5.00
Benzophenone - 4	0.10
Sodium citrate	0.60
Disodium undecylenamido MEA-sulfosuccinate solution	1.00
Triclosan	0.20
Salt	1.00
Laureth - 3	2.00
Sodium laureth sulphate	47.20
Melaleuca alternifolia	0.500
Phenoxyethanol	0.15
Colour	qs
Citric acid	0.10
Purified Water	to 100
High Surface Area Zinc Oxide	5.00

Stage 1

In a vessel sodium laureth sulphate, melaleuca alternifolia and high surface area zinc oxide were mixed until uniform.

Stage 2

In the base pan the triclosan was dispersed in cocamidopropyl betaine 30% and stirred for 5 minutes. The purified water was added and stirred well. Citric acid was added and stirred until dissolved followed by sodium citrate, which was stirred until dissolved and then stirred for a further 10 minutes. The mixture was cooled to 30-35°C. Then premixed phenoxyethanol in water, followed by benzophenone-4 in water were added. The colour was added followed by saline solution and water to make up to bulk.

Example 9 - Moisture Fluid (Control)

Ingredient	%
Glyceryl stearate	1.50
Steareth-2	2.00
Steareth-21	1.00
Cetyl Alcohol	1.00
Glycerin	1.00
Butylene Glycol	2.00
Purified Water	91.50

Stage 1

Glyceryl stearate, steareth-2, steareth-21 and cetyl alcohol were melted together at 70-75°C.

Stage 2

Glycerin was dissolved with stirring in water at 70-75°C.

Stage 3

Stage 1 was then added to stage 2 with stirring and then homogenised for 15 minutes. Water was added to the stirred mixture, which was subsequently cooled to 35°C. Butylene glycol was added and the mixture stirred until homogeneous and then made up to bulk with water.

Example 10 - Moisture Fluid + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Glyceryl stearate	1.50
Steareth-2	2.00
Steareth-21	1.00
Cetyl Alcohol	1.00
Glycerin	1.00
Butylene Glycol	2.00
Purified Water	86.50

Stage 1

Glyceryl stearate, steareth-2, steareth-21, cetyl alcohol and high surface area zinc oxide were melted together at 70-75°C.

Stage 2

Glycerin was dissolved with stirring, in water at 70-75°C.

Stage 3

Stage 1 was then added to stage 2 with stirring and then homogenised for 15 minutes. Water was added to the stirred mixture, which was subsequently cooled to 35°C. Butylene glycol was added and the mixture stirred until homogeneous and then made up to bulk with water.

Example 11 - Dandruff Shampoo (Control)

Ingredients	%
Magnesium aluminium silicate	0.30
Polyacrylic acid solution	1.50
Purified water	62.10
Preservative	0.08
Salt	1.00
Citric acid	0.02
Cocamidopropyl betaine 50%	5.00
Sodium laureth sulphate	30.0

Citric acid, salt and preservative were dissolved in water. Polyacrylic acid solution and magnesium aluminium silicate were added and the mixture homogenised. The mixture was then stirred for 20 minutes. Sodium laureth sulphate and cocamidopropyl betaine were added, followed by sufficient salt to obtain the correct viscosity.

Example 12 - Anti Dandruff Shampoo + High Surface Area Zinc Oxide

Ingredients	%
Magnesium aluminium silicate	0.30
Polyacrylic acid solution	1.50
Purified water	60.10

High Surface Area Zinc Oxide	2.00
Preservative	0.08
Salt	1.00
Citric acid	0.02
~~Cocamidopropyl betaine 50%~~	~~5.00~~
Sodium laureth sulphate	30.00

Citric acid, salt and preservative were dissolved in water. Polyacrylic acid solution and magnesium aluminium silicate were added and the mixture homogenised. The mixture was then stirred for 20 minutes. High surface area zinc oxide, sodium laureth sulphate and cocamidopropyl betaine were added, followed by sufficient salt to obtain the correct viscosity.

Example 13 - Mens Cooling Gel (Control)

Ingredients	%
Colour	qs
Purified Water	to 100
Perfume	0.30
Allantoin	0.10
Polysorbate 20	2.50
Xanthan Gum	1.80
Hamamelis virginiana solution	0.50
Glycerin	1.00
Phenoxyethanol	0.40
Butylene Glycol	2.00
Panthenol solution	0.50
Herbal extract	0.10

Allantoin, hamemelis virginia solution and herbal extract were mixed together. Then the colour in water, followed by xanthan gum were added. The mixture was stirred until homogeneous. Premixed panthenol, butylene glycol, phenoxyethanol and glycerin were then added to the mixture and stirred until uniform. The polysorbate 20 and perfume were homogenised together and then added to the bulk mixture, with sufficient water to make up to volume. The mixture was then stirred until it was uniform.

Example 14 - Mens Cooling Gel + High Surface Area Zinc Oxide

Ingredients	%
Purified Water	to 100
Colours	qs
Perfume	0.30
Allantoin	0.10
Polysorbate 20	2.50
Xanthan Gum	1.80
Hamamelis virginiana solution	0.50
Glycerin	1.00
Phenoxyethanol	0.40
Butylene Glycol	2.00
Panthenol solution	0.50
Herbal extract	0.10
High Surface Area Zinc Oxide	5.00

Allantoin, hamemelis virginia solution and herbal extract were mixed together. Then the colour in water, followed by xanthan gum were added. The mixture was stirred until homogeneous. Premixed panthenol, butylene glycol, phenoxyethanol and glycerin were then added to the mixture and stirred until uniform. The polysorbate 20, high surface area zinc oxide and perfume were

homogenised together then added to the bulk mixture, with sufficient water to make up to volume. The mixture was then stirred until it was uniform.

Example 15 - Mens Shower Gel (Control)

Ingredients	%
Polyethylene glycol-6 cocamide	1.00
Benzyl alcohol	0.75
Sodium methylparaben	0.15
Sodium laureth sulfate	9.86
Ammonium lauryl sulfate	10.80
Citric acid	0.17
Cocamidopropyl Betaine 50%	6.62
Lauryl glucoside solution	0.50
Purified Water	to 100
Polyethylene glycol-7 Glyceryl Cocoate	1.00
Salt	0.25
Triclosan	0.30
Herbal extract	0.60
Perfume	1.00
Colour	0qs
Polyquaternium - 10	0.25

Stage 1

Triclosan was added to polyethylene glycol-6 cocamide, warmed to 50°C and mixed until homogeneous. The mixture was cooled to 40°C, then perfume was added to the mixture which was stirred until uniform.

Stage 2

Polyquaternium-10 was added to water, warmed to 40°C with stirring, then further diluted with water. Salt, citric acid, benzyl alcohol, sodium

methylparaben, herbal extract, colour, polyethylene glycol-7 glyceryl cocoate and lauryl glucoside solution were added to the mixture and stirred until uniform.

Avoiding aeration, sodium laureth sulfate, ammonium lauryl sulfate and cocamidopropyl betaine 50% solution were added to the mixture, stirred until uniform and then cooled to 35°C.

Stage 3

Stage 1 was added to stage 2 with stirring until clear and uniform. Cold water was added to make up to bulk and the mixture stirred until uniform.

Example 16 - Mens Shower Gel + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Purified Water	to 100
Polyethylene glycol-6 cocamide	1.00
Benzyl alcohol	0.75
Sodium methylparaben	0.15
Sodium laureth sulfate	9.86
Ammonium lauryl sulfate	10.80
Citric acid	0.17
Cocamidopropyl Betaine 50%	6.62
Lauryl glucoside solution	0.50
Polyethylene glycol-7 Glyceryl Cocoate	1.00
Salt	0.25
Triclosan	0.30
Herbal extract	0.60
Perfume	1.00

Colour	qs
Polyquaternium - 10	0.25

Stage 1

Triclosan was added to polyethylene glycol-6 cocamide and high surface area zinc oxide warmed to 50°C and mixed until homogeneous. The mixture was cooled to 40°C, then perfume was added to the mixture which was stirred until uniform.

Stage 2

Polyquaternium-10 was added to water, warmed to 40°C with stirring, then further diluted with water. Salt, citric acid, benzyl alcohol, sodium methylparaben, herbal extract, colour, polyethylene glycol-7 glyceryl cocoate and lauryl glucoside solution were added to the mixture and stirred until unform.

Avoiding aeration, sodium laureth sulfate, ammonium lauryl sulfate and cocamidopropyl betaine 50% solution were added to the mixture, stirred until uniform and then cooled to 35°C.

Stage 3

Stage 1 was added to stage 2 with stirring until clear and uniform. Cold water was added to make up to bulk and the mixture stirred until uniform.

Example 17 - Mens Facial Wash (Control)

Ingredients	%
Hydroxyethylcellulose	1.25
Sodium laureth sulfate	6.57
Disodium undecylenamido MEA-sulfosuccinate	1.00

Butylene Glycol	2.00
Preservative	0.80
Benzoic acid	0.10
Polysorbate 20	2.00
Perfume	0.40
Herbal extract	0.60
Colour	qs
Purified Water	to 100

Stage 1

Butylene glycol and preservative were put in a stainless steel vessel and then mixed until uniform.

Stage 2

Perfume and polysorbate 20 were put in another container and mixed until uniform.

Stage 3

Hydroxyethylcellulose was mixed with some of the water in a steel container for 20-30 minutes until fully dispersed. Stage 1 was added, mixed and then the herbal extract, benzoic acid and colour were added and then mixed until fully dispersed.

Stage 4

Sodium laureth sulfate, and disodium undecylenamdo MEA-sulfosuccinate were added to stage 2 and mixed. Stage 2 was then added and mixed thoroughly. Cold water was added to make up to bulk. The bulk was stirred carefully to prevent foaming.

Example 18 - Mens Facial Wash + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Hydroxyethylcellulose	1.25
Sodium laureth sulfate	6.57
Disodium undecylenamido MEA-sulfosuccinate	1.00
Butylene Glycol	2.00
Preservative	0.80
Benzoic acid	0.10
Polysorbate 20	2.00
Perfume	0.40
Herbal extract	0.60
Colour	qs
Purified Water	to 100

Stage 1

Butylene glycol and preservative were put in a stainless steel vessel and then mixed until uniform.

Stage 2

Perfume, polysorbate 20 and high surface area zinc oxide were put in another container and mixed until uniform.

Stage 3

Hydroxyethylcellulose was mixed with some of the water in a stainless steel vessel for 20-30 minutes until fully dispersed. Stage 1 was added, mixed and then the herbal extract, benzoic acid and colour were added and then mixed until fully dispersed.

Stage 4

Sodium laureth sulfate and disodium undecylenamido MEA-sulfosuccinate were added to stage 3 and mixed. Stage 2 was then added and mixed throroughly. Cold water was added to make up to bulk. The bulk was stirred carefully to prevent foaming.

Example 19 - Translucent Complexion Base (Control)

Ingredients	%
Triethanolamine pure solution 80%	1.50
Methylparaben	0.20
Polyethylene glycol-5-ceteth-20	0.60
Allantoin	0.10
Hydrated silica	12.00
Stearic acid	12.00
Cetyl Alcohol	1.20
Butylene Glycol	10.00
Propylparaben	0.10
Dicaprylyl maleate	4.00
Alcohol denatured	2.00
Sodium C8-16 isoalkylsuccinyl lactoglobulin sulfonate	1.00
Alpha-glucan oligosaccharide	0.20
Herbal extract	0.40
Purified Water	51.68
Octyl palmitate	3.00
Butylated hydroxytoluene	0.02

Stage 1

Butylene glycol, allantoin, polypropylene glycol-5-ceteth 20 and methylparaben were added, whilst stirring, to the water at 70-75°C. Hydrated silica was then gradually added and mixed until uniform.

Stage 2

Stearic acid, cetyl alcohol, octyl palmitate, dicaprylyl maleate were melted together at 70-75°C. Using a silverson, butylated hydroxytoluene, propylparaben and triethanolamine pure solution 80% were added and the mixture stirred for 5 minutes.

Stage 3

Both stages were warmed to 70-75°C, then stage 2 was added to stage 1, and stirred for 5-10 minutes. The mixture was cooled to 40°C with stirring, then dicaprylyl maleate was added. The mixture was cooled to 30°C then alpha-glucan oligosaccharide in water, denatured alcohol, sodium C8-16 isoalkylsuccinyl lactoglobulin sulfonate, herbal extracts and water were added to the mixture. The mixture was then stirred until uniform.

Example 20 - Translucent Complexion Base + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Purified Water	46.68
Triethanolamine pure solution 80%	1.50
Methylparaben	0.20
Polypropylene glycol-5-ceteth -20	0.60
Allantoin	0.10

Hydrated silica	12.00
Stearic acid	12.00
Cetyl Alcohol	1.20
Butylene Glycol	10.00
Propylparaben	0.10
Dicaprylyl maleate	4.00
Alcohol denatured	2.00
Sodium C8-16 isoalkylsuccinyl lactoglobulin sulfonate	1.00
Alpha-glucan oligosaccharide	0.20
Herbal extract	0.40
Octyl palmitate	3.00
Butylated hydroxytoluene	0.02

Stage 1

Butylene glycol, allantoin, polypropylene glycol-5-ceteth 20 and methylparaben were added, whilst stirring, to the water at 70-75°C. Hydrated silica and high surface area zinc oxide was then gradually added and mixed until uniform.

Stage 2

Stearic acid, cetyl alcohol, octyl palmitate, dicaprylyl maleate were melted together at 70-75°C. Using a silverson, butylated hydroxytoluene, propylparaben and triethanolamine pure solution 80% were added and the mixture stirred for 5 minutes.

Stage 3

Both stages were warmed to 70-75°C, then stage 2 was added to stage 1, and stirred for 5-10 minutes. The mixture was cooled to 40°C with stirring, then dicaprylyl maleate was added. The mixture was cooled to 30°C then alpha-glucan oligosaccharide in water, denatured alcohol, sodium C8-16

isoalkylsuccinyl lactoglobulin sulfonate, herbal extracts and water were added to the mixture. The mixture was then stirred until uniform.

Example 21 - Pressed Powder (Control)

Ingredients	%
Sanitised Talc	90.72
Magnesium Stearate	5.00
Methylparaben	0.10
Red colour	0.23
Yellow colour	0.45
Paraffinum liquidum	2.10
Petrolatum	1.40

Sanitised talc, magnesium stearate, methylparaben and colours were mixed together for 10 minutes at high speed. Paraffinum liquidum and petrolatum were mixed together, heated to 75°C then sprayed into the bulk mixture at low speed. The bulk was mixed for 5 minutes, then passed twice through a hammer mill before being passed through a 30 mesh seive.

Example 22 - Pressed Powder + High Surface Area Zinc Oxide

Ingredients	%
High Surface Area Zinc Oxide	5.00
Sanitised talc	85.72
Magnesium Stearate	5.00
Methylparaben	0.10
Red colour	0.23
Yellow colour	0.45
Paraffinum liquidum	2.10
Petrolatum	1.40

Sanitised talc, magnesium stearate, methylparaben, high surface area zinc oxide and colours were mixed together for 10 minutes at high speed. Paraffinum liquidum and petrolatum were mixed together, heated to 75°C then sprayed into the bulk mixture at low speed. The bulk was mixed for 5 minutes, then passed twice through a hammer mill before being passed through a 30 mesh seive.

Example 23 - Cover Up Stick (Control)

Ingredient	%
Butylated hydroxyacetone	0.03
Carnauba	1.29
Candelilla Cera	1.01
Hydrocarbon wax consisting of Cera Microcristallina, paraffin and polyethylene	4.60
Cera Microcristallina	4.22
Synthetic wax	2.01
Propylparaben	0.10
Chalk	18.73
Triclosan	0.19
Allantoin	0.14
Pigment	21.56
Octyldodecanol	46.02

Pigments and chalk were added to the Diosna mixer and mixed for 30 minutes. The mix was then passed through the Mikro mill, then a vibrating sieve to give the colour preparation.

White wax, Carnauba and candelilla cera were added to a stainless steel steam jacketed pan fitted with a premier dispersator head, and melted together at 90-95°C. To the melt was added the hydrocarbon wax. When melted, ocyldodecanol was added and the mixture stirred.

The mixture was cooled to 85-90°C then propylparaben, butylated hydroxyacetone and triclosan were added to the stirred mixture, followed by allantoin and then by the colour preparation. The mixture was then stirred for a further ten minutes.

The mixture was then stirred through a 40 mesh sieve into a shallow tray and stirred slowly until set.

Example 24 - Cover Up Stick (With High Surface Area Zinc Oxide)

Ingredient	%
Chalk	23.31
Carnauba	1.29
Candelilla Cera	1.01
Hydrocarbon was consisting of Cera Microcristallina, paraffin and polyethylene	4.60
Cera Microcristallina	4.22
Butylated hydroxyacetone	0.03
Propylparaben	0.10
Octyldodecanol	46.02
Triclosan	0.19
Allantoin	0.14
Pigment	11.98
High Surface Area Zinc Oxide	5.00
Synthetic wax	2.01

Pigments, high surface area zinc oxide and chalk were added to the Diosna mixer and mixed for 30 minutes. The mix was then passed through the Mikro mill, then a vibrating sieve to give the colour preparation.

White wax, Carnauba and candelilla cera were added to a stainless steel steam jacketed pan fitted with a premier dispersator head, and melted together at 90-95°C. To the melt was added the hydrocarbon wax. When melted, ocyldodecanol was added and the mixture stirred.

The mixture was cooled to 85-90°C then propylparaben, butylated hydroxyacetone and triclosan were added to the stirred mixture, followed by allantoin and then by the colour preparation. The mixture was then stirred for a further ten minutes.

The mixture was then stirred through a 40 mesh sieve into a shallow tray and stirred slowly until set.

Example 25 - Baby Lotion Wipes (Control)

Ingredient	%
Sodium citrate	0.10
Purified water	75.03
Perfume	0.10
Polyaminopropyl biguanide	0.75
2-Bromo-2-Nitropropane-1,3-Diol	0.02
Cetrimonium bromide	0.50
A wax blend consisting of cetearyl alcohol, cetyl palmitate, cocoglycerides and glyceryl stearate	0.50
Steareth-10	1.50

An emulsifier blend consisting of glyceryl stearate and polyethylene glycol-30 stearate	1.50
Mineral oil	20.00

Stage 1

Steareth 10 was added to a base pan containing mineral oil at 70°C. The emulsifier blend and the wax blend were then added to the stirred mixture and melted together at 70°C.

Stage 2

Cetrimonium bromide was added to purified water at 70°C and mixed in a homogeniser.

Stage 3

Stage 1 was then added to stage 2, homogenised and stirred. Cold purified water was added and the mixture force cooled to 35°C. The perfume was then added, followed by polyaminopropyl biguanide and a solution of 2-bromo-2-nitropropane-1,3-diol in cold water. Water was then added to make up to bulk.

Example 26 - Baby Lotion Wipes (High Surface Area Zinc Oxide)

Ingredient	%
Sodium citrate	0.10
Purified water	70.03
Perfume	0.10
Polyaminopropyl biguanide	0.75
2-Bromo-2-Nitropropane-1,3-Diol	0.02
Cetrimonium bromide	0.50

A wax blend consisting of cetearyl alcohol, cetyl palmitate, cocoglycerides and glyceryl stearate	0.50
Steareth-10	1.50
An emulsifier blend consisting of glyceryl stearate and polyethylene glycol-30 stearate	1.50
Mineral oil	20.00
High Surface Area Zinc Oxide	5.00

Stage 1

Steareth 10 and high surface area zinc oxide was added to a base pan containing mineral oil at 70°C. The emulsifier blend and the wax blend were then added to the stirred mixture and melted together at 70°C.

Stage 2

Cetrimonium bromide was added to purified water at 70°C and mixed in a homogeniser.

Stage 3

Stage 1 was then added to stage 2, homogenised and stirred. Cold purified water was added and the mixture force cooled to 35°C. The perfume was then added, followed by polyaminopropyl biguanide and a solution of 2-bromo-2-nitropropane-1,3-diol in cold water. Water was then added to make up to bulk.

Example 27 - Nappy Rash Cream (Control)

Ingredient	%
Cetostearyl alcohol	2.00
Zinc oxide	7.50
Arachis Hypogaena	30.50
Cera Alba	10.00
Ricinus Communis	50.00

Arachis hypogaena, cera alba and cetostearyl alcohol were mixed together in a base pan at 65-70°C. The mixture was then pumped through an 80 mesh sieve into a mixing vessel. Zinc oxide was added to the mixture which was stirred for 5 minutes until homogeneous. Ricinus communis was then added to the mixture and the mixture stirred for 5 minutes until homogeneous.

Example 28 - Nappy Rash Cream (High Surface Area Zinc Oxide)

Ingredient	%
Cetearyl alcohol	2.00
High Surface Area Zinc Oxide	5.00
Arachis Hypogaena	30.50
Cera Alba	10.00
Ricinus Communis	52.50

Arachis hypogaena, cera alba and cetearyl alcohol were mixed together in a base pan at 65-70°C. The mixture was then pumped through an 80 mesh sieve into a mixing vessel. High surface area zinc oxide was added to the mixture which was stirred for 5 minutes until homogeneous. Ricinus communis was then added to the mixture and the mixture stirred for 5 minutes until homogeneous.

Example 29 - Licensed Nappy Cream (Control)

Ingredient	%
Purified water	44.40
p-chloro-m-cresol	0.10
Cetrimonium bromide	0.50
Cetearyl alcohol	5.00
Paraffinum liquidum	40.00
Dimethicone	10.00

Cetrimonium bromide and p-chloro-m-cresol were added to a base pan containing water at 60-65°C. A vacuum was applied to a fryma and the contents of the base pan transferred to the fryma via a sieve.

Dimethicone, paraffinum liquidum and cetearyl alcohol were added to the base pan, and warmed to 60-65°C. The contents of the base pan were then transferred to the fryma via a sieve. The contents of the fryma were stirred for 10 minutes. Maintaining the vacuum on the fryma, the stirred contents were cooled to 40°C until a smooth white cream was produced. The cream was then cooled to 35°C.

Example 30 - Licensed Nappy Cream (High Surface Area Zinc Oxide)

Ingredient	%
Purified water	39.40
p-chloro-m-cresol	0.10
Cetrimonium bromide	0.50
Cetearyl alcohol	5.00

Paraffinum liquidum	40.00
Dimethicone	10.00
High Surface Area Zinc Oxide	5.00

~~Cetrimonium bromide and p-chloro-m-cresol were added to a base pan~~ containing water at 60-65°C. A vacuum was applied to a fryma and the contents of the base pan transferred to the fryma via a sieve.

Dimethicone, paraffinum liquidum and cetearyl alcohol were added to the base pan, and warmed to 60-65°C. The contents of the base pan were then transferred to the fryma via a sieve. The contents of the fryma were stirred for 10 minutes. Maintaining the vacuum on the fryma, the stirred contents were cooled to 50-60°C when high surface area zinc oxide was added. The mixture was then stirred until a smooth white cream was produced. The cream was then cooled to 35°C and discharged to storage.

The antimicrobial action of the formulations of the present invention is illustrated by the methods given below. In the following experiments the zinc oxide used has a surface area greater than $90m^2/g$ and an average diameter of 10.47µm.

Method

The high surface area zinc oxide was dispersed at a maximum concentration of 25% in acetone. Two fold dilutions were prepared in acetone and aliquots of each dilution added to the appropriate agars to give a range of concentrations from 2.5% to 0.16%. Test plates and "no product" controls containing water only were streaked with the test organisms. These were then incubated as appropriate for three days.

The *P.ovale* was incubated on *P.ovale* growth medium, made using:-

Material	Quantity
Malt extract agar	60g
Ox bile - dessicated	20g
Tween 40	10.0ml
Glycerol mono-oleate	2.5ml
Water	to 1 litre

This was then incubated aerobically at 37°C for three days.

S.aureus was tested on Tryptone Soya Agar which was incubated aerobically for 37°C for two days.

P.acnes was tested on Brain Infusion Agar which was incubated annaerobically at 37°C for three days.

Results

	Water Control	Acetone Control	High Surface Area Zinc Oxide Concentrations				
			2.5%	1.25%	0.6%	0.31%	0.16%
P.ovale	Growth	Growth	No growth	No growth	No growth	No growth	No growth
P.acnes	Growth	Growth	No growth	No growth	No growth	No growth	No growth
S.aureus	Growth	Growth	No growth	No growth	No growth	No growth	No growth

Inhibition of growth was observed at the lowest concentration tested (0.16% in agar) for all three test organisms.

Experiment 2

Method

A second test was done at lower concentrations of the high surface area zinc oxide where the control of Zinc Oxide BP, and the test, high surface area zinc oxide, were suspended in acetone at 12.5% and aliquots were added to the agar to give a range of concentrations from 6250ppm to 98ppm.

The *P.ovale* was incubated on *P.ovale* growth medium, made using:-

Material	Quantity
Malt extract agar	60g
Ox bile - dessicated	20g
Tween 40	10.0ml
Glycerol mono-oleate	2.5ml
Water	to 1 litre

This was then incubated aerobically at 37°C for three days.

S.aureus was tested on Tryptone Soya Agar which was incubated aerobically at 37°C for two days.

P.acnes was tested on Brain Heart Infusion Agar which was incubated anaerobically at 37°C for three days.

A minimum inhibitory concentration was done to determine the minimum concentration at which the active material will inhibit the growth of the micro organisms to be tested.

Results

Table 2

	High Surface Area Zinc Oxide	Zinc Oxide BP Control
P.ovale	1562ppm	3125ppm
S.aureus	390ppm	>6250ppm
P.acnes	195ppm	195ppm

From this we can see that high surface area zinc oxide inhibits the growth of *P.ovale* and *S.aureus* at a lower concentration than the Zinc Oxide BP control. The high surface area zinc oxide inhibits the growth of *P.acnes* at the same concentration as the Zinc Oxide Control.

This means that the high surface area zinc oxide inhibits the growth of these three organisms better, or as well as the Zinc Oxide control. These results were obtained using the neat raw materials.

CLAIMS

1. Topical antimicrobial composition comprising a cosmetically acceptable diluent or carrier and an antimicrobially effective amount of high surface area zinc oxide powder, having a surface area between $30m^2/g$ and $100m^2/g$ and a particle size between 0.1 and 200μm in diameter.

2. A composition as claimed in claim 1 where the surface area of the high surface area zinc oxide is between 90 and $100m^2/g$ and the particle size is between 0.1 and 20.5μm in diameter.

3. A composition as claimed in claim 1 where the high surface area zinc oxide is present from 1 to 10% by weight of the total composition.

4. A composition as claimed in claim 1 where the high surface area zinc oxide is present from 3 to 8% by weight of the total composition.

5. A composition as claimed in claim 1 where the high surface area zinc oxide is present from 4 to 6% by weight of the total composition.

6. The use of high surface area zinc oxide in the treatment of acne, athletes foot, nappy rash and dandruff.

7. The use of high surface area zinc oxide in the preparation of a medicament for the treatment of acne, athletes foot, nappy rash and dandruff.